REMARKS

Reconsderation and reexamination of this application is respectfully requested.

SUMMARY OF THE FACTS SET FORTH IN THE SPECIFICATION:

1.Microwater is water treated electrolytically. The pH of microwater is NO lower than 2.5.

page 2

2. Activated water is water produced chemically (by the applicant). It is typicallyy made having a pH in a range down to 0.5 to which water is added to bring the pH up to 1.5----

page 9

3. A direct quote from the independent BIOVIR TESTING laboratory who performed the tests on disinfecting power for the microbes reported in the specification:

> The test sampls (from the applicant) have demonstrated a capability of a 99.995% bactericidal effect within five minutes. The lower the SUSTAINABLE pH, the greater is the bactericidal power of the product. (specification, page 15)

4 Both Activated water and Microwater are preferred over other acidic disinfectants for use on human skin because neither disinfectant "burns" the skin. ---- page 10

5 Activated water is more effective than Microwater because Activated water can be produced having a lower pH (as low as 0.5) than Microwater which (as produced has a lowst pH of 2.5. Activated water is typically diluted (for use) by water addition to a pH (1.5)

6. The patent claims of this application are directed toward a method of disinfecting the skin by applying a disinfectant that comprises activated water manufactured by the chemical process described in U.S.Patent 6,331,514. The advantages of Activated Water over Microwater is the ability to apply Activated water having a pH as low as 1.5 andlower/

7. A terminal disclaimer has been granted to the Applicant which rules out citation of 6,331514 as a reference against this application for patent.

By way of offering a possible explanation as to "how activated water "contains cations but not anions to establish a pH below 7, it is conjectured that the method of preparing activated water and microwater results in an aqueous medium where each cation (H+) occupies a small volume surrounded by a large volume of distributed negative charge. This model would satisfy the "balance of charge" requirement which is required for all solutions.

In view of the foregoing statements of fact, presented in the application, the following quotation from the Office Action has no relevance to prosecution of the application

The Examiner states:

> "Applicant's admission regarding the prior art page 2 lines 6-7 of the specification teaches thatt "the acid microwater has been found to have commercially viable bactericidal properties when used in the lowest pH range (2.5) attainable (reported) Note that Microwater TM distributed by Optimum Health Institute, San Mateo, Ca.. Thus pH below 2. For sterilizing or disinfecting solutions is known in the art."

The Applicant submits:

Contrary to the Examiner's statement, references have NOT been disclosed that:

1. claim a disinfectant for the skin where the pH is less than 2.5; nor

2. include Microwater; nor

3. include any water that has a pH less than 2.5 and does not contain anions

The Examiner's statement: " Thus pH below 2. for sterilizing or disinfecting solutions is known in the art." is a misquote of the specification regarding Microwater. What the specification says is that 2.7 is the lowest pH value OF MICROWATER, see page 9 of the specification reported (by Dr, Friedlander, director of the Optimum Health Institute) using the electrolysis method to produce Microwater. In contrast, activated water can be produced by the chemical process disclosed by the Applicant having a pH as low as 0.5 although the lowest pH of activated water disclosed in the specification is 1.5 (see page 9). This observation was also reported to the undersigned by Dr. Friedlander supplied with samples of activated water by the Applicant). Dr. Friedlander has direct experience with BOTH activated water AND Microwater.

The wording in the Background of the specification regarding the use of Microwater is confusing. Therefore, the Background is amended herein to describe the use of Microwater as a disinfectant.

The amended Background states,

> "The production of Microwater having a pH less than 2.5 is not known. It follows that the use of Microwater as a disinfectant on the skin where the pH is less than 2.5, is also not known."

Therefore the 35 U.S.C. 103 rejection based on the use of Microwater in view of the references cited by the Examiner is not supported because the claim is directed toward a method for using a disinfectant on skin in which the pH is less than 2.5 and will not burn the skin.

The distinction between the present invenion and MICROWATER is that the ACTIVATED WATER claimed by the applicant in formulating his disinfectant by a chemical process has different properties than the MICROWATER ™ formulated by an electrolytic process.

The difference is manifested as:

1. a lower pH (0.5) attainable by the chemical process used to produce activated water compared to the lowest pH (2.5) attainable by the electrolytic process used to generate "acid" microwater. The lowest pH for activated water disclosed in the specification is 1.5 (page 9) however it should be noted that the activated water generated by the chemical process of this invention is typically as low as 0.5. In practice, the concentrate of Activated water (as manufactured) is diluted with water to provide a pH of 1.5 for use as a disinfectant. Activated water having a pH of 1.5 was used in the examples stated and reported in the specification.

2. a greater stability (shelf-life) that characterizes the activated water than characterizes micro water.

According to the statement of Dr. Friedlander, Microwater is most effective when it is used immediately after its manufcture and its potency declines in a period of days after its manufacture; whereas

Activated water has a shelf life of years. For example, the undersigned has a gallon of activated water having a pH of 0.5 that is several years old.

The foregoing remarks are confirmed by:

Dr. Bernd Freidlander, founder of Ultimate Health Institute and manufactuer and distributer of Microwater; and

Steven Wirzburger, Applicant and inventor of the process for manufacturing activated water.

The undersigned is a personal friend of both Fiedlander and Wurzburger and has personal knowledge that Friedlander has received samples of Activated Water from Wurzburger wherein he (Friedlander) stated to the undersigned that the pH was 0.5. He also stated that the lowest pH of the Microwater produced by the electrolytic process was "3.0, sometimes a "HIGH" 2. MEANING CLOSE TO 3.

In view of the identical chemical compositions, (being H2O) for both activated water and microwater, the only way to differentiate between the two liquids to establish a patentable distinction is by a description of the method of preparation-- chemical vs. electrolytic.

Although the Applicant does not wish to be bound by theory, he suggests that the different method of preparation (chemical vs. electrolytic) results in a difference of water structure (perhaps a difference in cluster size) that results in a greater attainable H+ concentration in activated water than in microwater.

The importance of the cation and anion in determining the effectiveness of a disinfectant is suggested by the mechanism by which a disinfectant operates.

The cation (H+) oxidizes and destroys microbes. The anion produces a reducing action that results in breakdown (burning) of molecular structure of the cells of the skin.

Therefore, the ideal agent for removing the microbes on the skin and listed in the specification provides a high concentration of H+ and a minimal concentration of anions.

The activated water used in the disinfectant of this invention with low pH (1.5) can be applied to the skin and kill microbes **without attacking the skin.**

Activated water, having a pH of 1.5 as reported in the specification, has 10 times the concentration of H+ ions compared to microwater having the lowest attainable pH (2.5).

See page 10 for a statement regarding the compatibility of the disinfectant with human skin.

Of course, both activated water and microwater have "0" concentration of anions so that both Activated water and Microwater are a major improvement over common aqueous disinfectants of comparable pH but containing anions such as Cl-.

However the activated water of this invention is superior to Microwater bcause Activated water can be provided having a lower pH.

Incidentally, several years ago, the undersigned introduced Wurzburger (the Applicant) to Friedlander. They have exchanged samples and generally exchanged information of personal experiences re Microwater and Activated water and they both confirm my understanding as presented above.

Freidlander confirmed to me that the pH of the activated water given to him by Wurzburger was much lower (less than 1.0) than the microwater that Friedlander produced by electrolysis. (3.0 or greater)

All of these observations show that the activated water produced chemically and used as a disinfectant by the applicant has a different structure than the Microwater produced

electrolytically by Friedlander and that the activated water is a superior product than the microwater in terms of disinfecting strength (lower achievable pH), cost, and shelf life. This difference MAY be cluster size although the applicant does not wish to be bound by this conjecture.

CLAIM REJECTION UNDER 35 U.S.C. 103

The Examiner states:

> " It is noted that the pharmceutical art is unpredictable requiring each embodiment to be assessed for physiologic activity. In re Fisher, 427 F.2d 833, 166 USPQ indicates that the more unpredicatable an area is, the more specific embodiment is necessary in order to satisfy the statute."

In view of this statement of case law cited by the Examiner, the references cited by the 35 USC 103 rejection of the instant claims are not applicable in the sense that, if a compound (e.g., oxalic acid) is an effective disinfectant in one environment, it does not necessarily follow that the same disinfectant will be effective in another environment.

The Examiner states:

" Claims 7 - 27 are rejected under 35USC 103(a) as being unpatentable over Wachman et al in view of Applicant's admission regarding the prior art in the specification (see page 2) "

The Applicant submits: The Examiner misinterprets the Applicant's statement.

Microwater does not have a pH less than 2.5.

The Applicant submits: claim 28 which replaces cancelled claim 7 reads in part:

"an amount of water added to said solution of activated water to provide activated water having a pH below 2.5"

The Examiner further states:

> Wachman et al discloses that an exemplified sterilizing composition against a wide range of virus, bacterial and fungi comprise water, sodium nitrate the instant quaternary ammonium compounds, isopropanol) and carrier.

The Applicant submits:

Wachman's only reference to pH is in the Abstract:

"The sterilant is especially useful between pH 4 to 8"

and col. 11, lines line 42:

" which are effective only from about pH 4 to 9 with a preferred range being 5 to 8."

In other words, it is not obvious that even though the constituents quaternary ammonium compounds, isopropanol and carrier are efective against one group of microbes in an environment of pH 5 to 8, that they would also be effective against another group of microbes in activated water having a pH below 2.5.

The Applicant adds quaternary amine to activated water to perform a DIFFERENT FUNCTION than does quaternary amine added to Wachman's disinfectant. The Applicant addition is for the purpose of retaining activated water on the skin, taking advantage of the hygroscopic nature of the quaternary amine (thereby extending the life of the disinfectant). Wachman's purpose is to add greater disinfecting power to his application.

Furthermore, Wachman says NOTHING about the application of his sterilizing agent to the Skin. His disinfectant is directed to application on "hard or environmental surfaces

(nonabsorbing) such as medical or dental equipment" (col. 4, line 1) and "hard surfaces of wood, metal, plastics, ceramics or glasses" (col.25) The Applicant's invention is directed specifically toward application to skin.

As the Examiner states: "Wachman does not expressly state that the pH is below 2.5"

The Appliant submits:

Wachman no where states that Wachman's pH (5.0) is anywhere near 2. 5. Note that a difference in ion concentration between 2.5 and 5.0 is 500:1

The Examiner states:

> Andrews et al teaches that lactic acid as an antifungal antibactrial agent is useful for disinfecting and antimicrobial composition which also comprises glycerol (col 1, 41 ; Example 5 at col. 6 lines 55-65)

The Applicant submits;

There is not one mention of the term pH in the Andrews patent. Andrews discloses making a concentrate which contains, at most, 30% lactic acid as a fatty acid. The concentrate is diluted in water so that the dilution of fatty acid is about 750:1. Furthermore, fatty acids are well known to be WEAK acids so that any contribution to the pH is minimal so that the Andrews disinfectant is close to neutral pH. Based on the composition of disinfectant disclosed in Andrews, there is no suggestion in Andrews to mix lactic acid with either activated water, or microwater or any other aqueous solution where the pH is below 2.5. The suggestion comes ONLY from the instant specification.

Andrews lists glyceryl monolaurate ,an ester, NOT GLYCERIN as a constituent in his disifectant COL 6, line 55.

Andrews (col. 1, line 41) discloses combinations of monolaurin caprylic and capric acids with lactic acid useful as a shampoo . This suggests the formation of esters of monolaurin and the acids but most certainly not an aqueous solution having a pH below 2.5.

The foregoing disclosures in no way suggest combining lactic acid with activated water to

provide an anti septic treatment for human skin that would kill 99.995% microbes in five minutes.

The Examiner states:

> "Jootes teaches that oxalic acid is used in sterilizing or disinfecting composition. In particular Jooste discloses that acidic solutions therein are in the range of 2 - 6 (see col. 6, lines 33- 35)"

The Applicant submits:

Jootse discloses "a halogen containing compound which is effective as a sterilizing agent and a stabilizing agent containing sulfur (to stabilize the halogen containing compound). Particularly useful such compounds (as stabilizing agents) <u>are those having an available sulfur such as ---oxalic acid and it salts."</u>

Oxalic acid contains no sulfur so this statement can only be construed to mean a sulfur containing ester of oxalic acid and NOT oxalic acid per se.

The disinfectan with stabilizer is maintained separate from the an activator until the moment of use when the activator is added to the stabilized sterilizing agent to reduce the pH of the stabilized solution (disinfectant" to below 7, and preferably to at least 6.

In other words, although the pH of the activator may be in the range 2 - 6, THE DISINFECTANT MIXED WITH THE ACTIVATOR HAS A PH OF NO LESS THAN 6. The activator has a pH of 2 - 6 until it is added to the disinfectant after which the pH of the final disinfecting solution is above 6.

The Examiner states:

> "It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adjust the pH to below 2.5 and to optimize the amount of salts and acid in volume percentage and add lactic acid in the composition of Wachman et alL"

The Examiner is wrong. If the pH were adjusted to below 2.5, any acid that would effectively reduce the pH to below 2.5 would "burn" the skin as recited above. He would have to add the activated water of this invention as disclosed by the present specification.

In view of the above, it is believed that all of the reasons for rejecting the claims 7 - 27 under 35 USC 103 have been overcome and that claim 28 is in condition for allowance. All remainign claims depend from claim 28 and therefore should be allowed for at least the same reasonsas for allowing claim 28 Allowance of all remaining claims is earnestly solicited.

Respectfully submitted,

Robert S. Smith

-12-